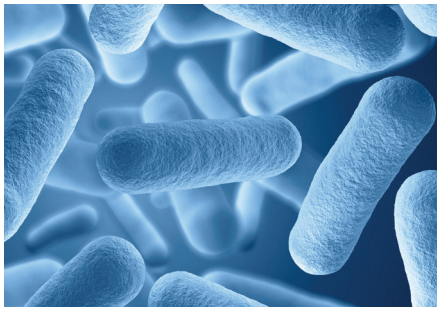
On-Site Generation



UNDERSTANDING HOW THE ON-SITE GENERATION OF ANTIMICROBIALS IS REGULATED

On-site generation of antimicrobials using electrically activated water, liquified ozone, and other technologies is increasing in popularity in a number of commercial markets. This shift has prompted prospective end-users to ask questions regarding regulatory issues. Specifically, are these devices that generate antimicrobials on site regulated by the United States Environmental Protection Agency (EPA) and other governing bodies around the world? The answer, in the case of the EPA, is yes.

Pesticide devices are regulated per the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which mandates that the EPA regulate the use and sale of pesticides to protect human health and preserve the environment. FIFRA defines a pesticide device as "an instrument or contrivance (other than a firearm) that is used to destroy, repel, trap or mitigate (lessen the severity of) any pest such as insects, weeds, rodents, certain other animals, birds, mold/mildew, bacteria and viruses."

Antimicrobial pesticide devices typically mitigate microbial organisms (such as bacteria and viruses) using physical means. For example, some devices trap bacteria via filtration, while others generate a substance, such as ozone, to mitigate microbial pests.

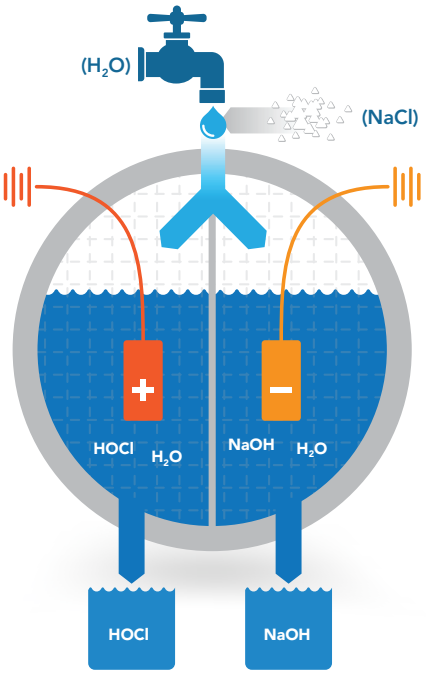
By contrast, a liquid antimicrobial pesticide product (not a device) only utilizes formulated substances with an active ingredient to mitigate pests. Liquid disinfectants are a common example of these products.

REQUIREMENTS FOR PESTICIDE DEVICES & PRODUCTS

Currently, the EPA requires the registration of liquid pesticide products prior to selling, but does not require the registration for pesticide devices. While the EPA does not require the registration of pesticide devices, there are six states that do require registration prior to placing product on the market in that state. These states include Colorado, Indiana, Oklahoma, New Mexico, Wyoming, and the District of Columbia. Users in these states should verify registration of the device.

As stated, the EPA exempts pesticide device registration, but does regulate devices per 40 CFR part 152.500, which requires compliance with production, labeling and testing requirements.

Antimicrobial pesticide devices must be manufactured in an EPA-registered pesticide production establishment. Device manufacturers must acquire an EPA company number before registering a production facility. The EPA-assigned establishment number must be incorporated into the device labeling. Users should check labels to ensure devices are manufactured at registered facilities.



Electrically Activated Water (EAW) is one example of On-Site Generation (OSG) products that are pesticide devices regulated by the EPA.

All labels and labeling for an antimicrobial pesticide device must comply with the same requirements as a registered product. Pesticide *labels* are attached to the device or associated containers. Pesticide *labeling* includes all other collateral materials that support the marketing and sale of the device, including websites, sell sheets, trade exhibits and other supporting materials. All label and labeling claims must be supported by EPA acceptable product specific data.

The selling company must generate all data that typically supports a pesticide product registration and keep that data on file in the event of an EPA audit. There are two categories of efficacy data relating to antimicrobial pesticide devices, public health or non-public health data.

PUBLIC HEALTH vs NON–PUBLIC HEALTH CLAIMS

The Antimicrobial Division of the EPA requires efficacy data to support public health claims. Data must be generated per Good Laboratory Practice (GLP) guidelines and EPA accepted testing methods. This affects a range of products, such as sterilants, disinfectants, tuberculocides, fungicides, virucides and sanitizers. Since the EPA does not require submission of this data for devices, end-users of antimicrobial pesticide devices should request data summary reports from the device manufacturers to ensure GLP and EPA compliance.

These data reports must be specific to the device, technology, and output. A company cannot cite generic data for a general technology (such as ozone), as devices that generate similar outputs are typically not identical.

Non-public health antimicrobial pesticide devices must display a label claim to control microorganisms of economic or aesthetic significance, not disease-causing organisms. Examples include products used to control odor-causing bacteria. Data is required to support non-public health claims, but testing does not need to adhere to GLP guidelines.

The complexity of antimicrobial pesticide device regulation requires thoughtful planning and vigilant regulatory management during all stages of the product lifecycle. Because the increasing number of antimicrobial pesticide devices on the market offer a variety of claims, end-users are encouraged to ask questions and request confirmation of efficacy testing from manufacturers.

References:

1. U.S Environmental Protection Agency. “Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)”. 7 U.S.C. 136-136y
2. 40 Code of Federal Regulations (CFR) § part 152.500, Requirements for Devices
3. Office of Pesticide Programs, Environmental Protection Agency. Pesticide Registration Manual, Chapter 13, Devices
4. Pesticide Devices: A Guide for Consumers, (http://www.epa.gov/pesticides/factsheets/devices.htm)

ABOUT THE AUTHOR

Dr. Brian C. Brosdahl is the Managing Consultant for AP Strategies, which offers expert consulting services to businesses that acquire, fund, develop, manufacture or sell antimicrobial products, as well as the organizations that use those products. Dr. Brosdahl has extensive experience working directly with the Antimicrobial Division of the EPA and with the Infection Control Device Branch of the FDA. He has worked in Europe with the Biocide Product Regulation (BPR), as well as various other international regulatory authorities. He has negotiated hundreds of product approvals within the United States and foreign regulatory agencies, ranging from small product changes to new product registrations. Past positions include President & CEO of ATS Labs, Vice President of Global R&D for Smiths Medical, General Manager for Sterilucent, Inc. and Director of International Product Registration for Ecolab, Inc. He has a Ph.D. in Public Health Policy, an M.B.A. in Management and an M.S. in Environmental Engineering.